Summary Information Format for the Importation of Veterinary Biological Products into the United States from Countries where Foreign Animal Diseases Exist and Other Specified Countries

I. INTRODUCTION

The purpose of this Summary Information Format (SIF) is to provide the Center for Veterinary Biologics, APHIS, with the necessary information to conduct risk analyses for proposals to import veterinary biological products from countries that represent a risk for the introduction of foreign animal disease into the United States. This includes proposals to import Master Seed microorganisms or veterinary biological products from: 1) Countries where foreign animal diseases exist, or 2) Other specified countries that supplement their national meat supply by the importation of fresh, chilled, or frozen meat of ruminants or swine from, or have common land borders with countries where foreign animal diseases exist, as provided in 9 CFR Part 94.

This SIF should be completed and submitted to APHIS in support of applications for: 1) A U.S. Veterinary Biological Product License Application (9 CFR Part 102.5) for a product being produced from a Master Seed microorganism(s) imported to the United States under a U.S. Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (9 CFR Part 122.2); 2) a U.S. Veterinary Biological Product Permit for Distribution and Sale (9 CFR Part 104.5); or 3) a U.S. Veterinary Biological Permit for Research and Evaluation (9 CFR Part 104.4) involving a request to conduct field studies in accordance with 9 CFR Part 103.3.

For proposals to import veterinary biological products containing more than one antigenic fraction, a separate SIF should be completed for each Master Seed microorganism.

A. Identify Application

B. Specific Proposal

II. RESEARCH AND DEVELOPMENT

A. Research Facility

1. Identify all facilities involved in development of Master Seed and Master Cells from date(s) of isolation

2. Location and description of the facility or facilities

3. Biocontainment

(a) Air handling system

(b) Containment equipment

(c) Operational and validation procedures

4. Other Microorganisms Maintained in the Research Facility or Facilities Involved in the Development of the Master Seed and Master Cells

(a) Identity and source

(b) Location and storage conditions

(c) Purpose for maintaining and handling of these microorganisms

(d) Procedures used to prevent cross contamination of Master Seed and Master Cells during development

B. Characterization of the Vaccine Microorganism

1. Development of the vaccine strain

(a) Parental microorganism

(i) Identity of parental strain

(ii) Genetic markers

(b) Source and isolation of the vaccine microorganism

(c) Procedures used to attenuate the vaccine microorganism

(d) Passage history of the vaccine microorganism

(e) Potential contaminating microorganisms exotic to the U.S.

(f) Purity and extraneous agents testing, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

(g) Screening methods and protocols used in the identification and purification of the vaccine microorganism

(h) Characterization of the Master Seed

(i) Master Seed designation

(ii) Identification of the Master Seed, including methods and protocols

(iii) Purity and extraneous agents testing of the Master Seed, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

(iv) Genetic stability of the Master Seed microorganism at passage level n and the highest passage level used in production

2. Ingredients of animal origin used during development of the vaccine microorganism

(a) Primary cells

(i) Identity and source

(ii) Preparation

(iii) Potential contaminating microorganisms exotic to the U.S.

(iv) Purity and extraneous agents testing, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

(v) Sensitivity of cells to the growth or replication of potential contaminating microorganisms exotic to the U.S.

(b) Cell Lines

(i) Identity and source

(ii) Procedures for confirming the identity of the cell line

(iii) Potential contaminating microorganisms exotic to the U.S.

(iv) Purity and extraneous agents testing, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

(v) Sensitivity of cells to the growth or replication of potential contaminating microorganisms exotic to the U.S.

(c) Serum and other reagents of animal origin

(i) Identity and source

(ii) Sterilization procedures

(iii) Potential contaminating microorganisms exotic to the U.S.

(iv) Purity and extraneous agents testing, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

III. PRODUCTION

A. Production Facility

1. Location and description of the facility

2. Blue prints, plot plans, and legends

3. Biocontainment

(a) Air handling system

(b) Containment equipment

(c) Operational procedures

4. Products produced in the facility and other microorganisms maintained in the facility

(a) Procedures to prevent cross-contamination

(b) Decontamination procedures between production runs

(c) Validation procedures

(d) Purpose for maintaining microorganisms not used in production

B. Production Procedures

1. Cell culture and harvest procedures

2. Procedures for preparing the product from harvested cultures

3. Inactivation procedures for killed products

(a) Validation of inactivation procedures for the product microorganism

(b) Validation of inactivation procedures for potential extraneous agents

4. Ingredients of animal origin and cells used in production

(a) Identity and source

(b) Quality control and/or sterilization procedures

(c) Potential contaminating microorganisms exotic to the U.S.

(d) Purity and extraneous agents testing, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

(e) Sensitivity of cells to the growth or replication of potential contaminating microorganisms exotic to the U.S.

5. Production media and additives used in production

(a) Identity and source

(b) Quality control and/or sterilization procedures

(c) Purity testing

6. Validation procedures during production

7. In-process testing procedures

8. Final product purity testing, including the sensitivity of testing procedures for potential contaminating microorganisms exotic to the U.S.

9. Packaging, labeling, and storage conditions for the final container samples

10. Proposed shipping procedures and conditions

11. Any other procedures employed to detect, inactivate, remove or reduce the presence of potential contaminating microorganisms exotic to the U.S.